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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/585,792      | 07/12/2006  | Mart-Jan T. Blauwhoff | 1704 WO/US          | 7351             |

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03/24/2010

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| EXAMINER |
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KUMAR, SHAIENDRA

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| ART UNIT | PAPER NUMBER |
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1621

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| MAIL DATE | DELIVERY MODE |
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03/24/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/585,792 | <b>Applicant(s)</b><br>BLAUWHOFF ET AL. |  |
|                              | <b>Examiner</b><br>SHAIENDRA KUMAR   | <b>Art Unit</b><br>1621                 |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/7/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-22 are pending in this application.

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 8/7/06 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

#### ***Drawings***

The drawings are objected to because legends are not legible and are not clear. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

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pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5, 7-9, 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for technetium-99m, does not reasonably provide enablement for tritium,  $^{14}\text{C}$ ,  $^{13}\text{C}$ ,  $^{125}\text{I}$ ,  $^{32}\text{P}$  or for that matter so many other existing radionuclei. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant specification is enabled for only technetium-99m and there is no enablement for any other radionuclei, as to how to make and use the same. There is nothing in the specification that suggests that radiolabeling with technetium is similar to radiolabeling with  $^{32}\text{P}$  or  $^{125}\text{I}$  or  $^{14}\text{C}$  or  $^{13}\text{C}$  or  $^3\text{H}$  etc.

Claim 6 is objected to under 37 CFR 1.75(c) as claim does not refer to a preceding claim. Note this claim depends from claim 16. Correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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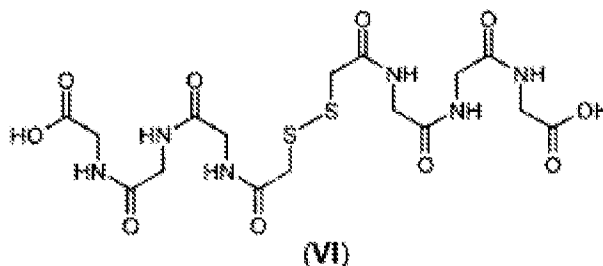
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Noll et al(Nucl. Med. Biol, 1995) or EP 0 483 704.

Instant claims are directed to

1. Method for preparing mercaptoacetyl triglycine labeled with a radionuclide, comprising:  
adding a radionuclide to a solution that comprises a mercaptoacetyl triglycine dimer of formula VI and a reducing agent; and



heating the solution at least after the adding.

2. Method as claimed in claim 1, wherein the solution that comprises the mercaptoacetyl triglycine dimer and the reducing agent is obtained by reconstitution from a lyophilisate.
3. Method as claimed in claim 1, wherein the radionuclide is technetium-99m.
4. Method as claimed in claim 3, wherein the adding comprises adding  $^{99m}\text{Tc}$ -pertechnetate.
5. Method as claimed in claim 1, wherein the reducing agent is selected from stannous salts.
6. Method as claimed in claim 16, wherein the transfer ligand is selected from sodium tartrate, glycine, citrate, malonate, gluconate, malate, lactate, pyrophosphate, and glucoheptonate.
7. Method as claimed in claim 1, wherein the heating comprises heating the solution to 80-120°C.
8. Method as claimed in claim 1, wherein the heating occurs for a duration of 5-60 minutes.

Noll et al, anticipate instant claims when it teaches all the elements of various claim, see page 1059, Fig 3, and Table I. Likewise, EP'704 anticipate instant claims

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when it teaches all the elements of the instant claims, see the abstract, page 3, and example 2.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of EP'704 and Noll et al .

EP'704 have been described supra. Basically, the reference teach every element except the kit. See abstract, Examples 2-5. The difference between the reference and herein claimed subject matter is the reference does not mention a kit.

Noll et al is teaching that a kit is well known in the art for the preparation of formulation of the radionuclide of the MAG-3, see page 1059. Any difference between the reference and herein claimed subject matter may be the exact ratio of various ingredients.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify EP'704 and prepare the kit as taught by Noll et al, because the latter reference is expressly teaching that a kit is old in the art for the preparation of radiopharmaceutical material.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on M-F, 7:30AM-5:00PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Kumar

3/23/10

/SHAILENDRA KUMAR/

Primary Examiner, Art Unit 1621